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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/674,598 | 09/30/2003 | Edmund F. La Gamma | 2671/60435-AA | 4490 |

7590 10/07/2005
John P. White, Esq.
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New York, NY 10036

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| EXAMINER |
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KELLY, ROBERT M

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| ART UNIT | PAPER NUMBER |
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1633

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,598

Applicant(s)

LA GAMMA ET AL.

Examiner

Robert M. Kelly

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/30/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Claims 65-75 are presently pending and considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 65-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,106,827. Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Claims 67-75 of the instant Application are similar to claims 1-10 of U.S. Patent No. 6,106,827, however they are broader, encompassing any promoter for regulating expression of the selectable marker, rather than being limited to GFAP or RSV, therefore, the new claims encompass the invention of the patent. It is further noted that the GFAP promoter is one such promoter taught by the instant Application (SPECIFICATION, p. 25), and the thymidine kinase promoter is also taught in the specification (SPECIFICATION, p. 25). Similarly, the patent also teaches the GFAP promoter (col. 11, last paragraph) and TK promoter (col. 11, last paragraph).

Hence, because the presently considered Application is drawn to a broader genus than the issued patent, and because the present Application defines the specific promoters already allowed, these claims are subject to obviousness-type double patenting.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 65 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims read on astrocytes existing in nature, untouched by the hand of man. Specifically, the DNA could read on such in nature, e.g., transposons, and the selectable marker could be any protein, as they could be selectable by way of antibody or northern blot. It is suggested that Applicant amend the claim to recite "An isolated ...".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 74 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 74 is rejected because the metes and bounds of such cell line "resulting from the genetically-modified astrocyte...", are not clear. To wit, further modification could remove the

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non-viral genetic modification, yielding the equivalent original cell, or further modification could yield a completely different cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 74 is rejected under 35 U.S.C. 102(b) as being anticipated by Alliot, et al. (1991)

Proc. Natl. Acad. Sci., USA, 88: 1541-45.

Alliot teaches cultures of astrocytes growing in conditioned media (ABSTRACT).

It is noted that this rejection is held because of the breadth of Applicant's claim, encompassing any astrocyte derived from a cell produced by Applicant's method.

Note: re Prosecution History

The Examiner has reviewed Application Nos. 09/643,334 and 08/862,438. A review of 09/643,334 indicated that the presently considered claims are the same claims at the time of closure of 09/643,334. In 09/643,334, the claims only had a pending rejection for double, similar to the rejection given above. In addition, except the aforementioned rejections, the Examiner agrees with the prior Examiner's consideration of the case and has found no other relevant art to maintain other new rejections. Hence, the only pending rejection on the instant claims is the aforementioned double-patenting, 101, 112, second paragraph, and art rejection.

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In addition, the Attorney of record was contacted twice during of 9/19/05, in order to ask for a terminal-disclaimer to be filed and to amend the claims to overcome the aforementioned rejections. However, the Attorney of record did not return the Examiner's messages, therefore, the above-provided rejections are the only presently pending rejection on the claims.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

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